PSJ4 SOL Opp Exh 36

CardinalHealth

To: Dan Tolar
From: Carolyn McPherson
Date: July 27, 2006
Subject: June 2006 Regulatory Compliance Review

From **June 26 – June 29, 2006**, a Regulatory Compliance Review was conducted at the Pharmaceutical Distribution (Dohmen) facility in **Birmingham, AL** by Don Bennett. The end result of the review was a confidential report that detailed the findings and made specific recommendations for improvement.

Each recommendation has been coded according to the degree of risk for non-compliance and the degree of difficulty of implementation. The coding system is as follows:

Risk for Non-Compliance	*Difficulty of Implementation*
A - High	1 - High
B - Medium	2 - Medium
C - Low	3 - Low

A recommendation that has a code of A-2 would have potentially severe consequences for non-compliance and a medium degree of difficulty for implementation.

Please review and return to me with your action steps to ensure compliance by *August 25, 2006*. Responses may be submitted via e-mail. If you have any questions about the report, you may reach the Cardinal Compliance office at (614) 757-7169.

Attachment

cc:

Gary Dolch	Kevin Kannally	Eric Brantley	Kim Cecere
Ed Fry	Martha Huston	Don Bennett	Goldie Clemens
Claude Grant	Steve Reardon	Elaine Trautman	Lynn Rider
Mike Duffy	Jon Shifflett	Kristeen Nicholson-Miller	

CONFIDENTIAL

July 27, 2006

REGULATORY COMPLIANCE REVIEW
JUNE 2006
PHARMACEUTICAL DISTRIBUTION
BIRMINGHAM, AL

Observations & Recommendations

Executive Summary

Pharmaceutical Distribution
Birmingham, AL
6/26/2006-6/29/2006

CORRECTIVE ACTIONS: 39 (18 - A; 17 – B; 4 – C)

SIGNIFICANT ISSUES:

- **DEA**

DEA Theft/Loss reports are not submitted to DEA within 7 days of discovery.

Customers were receiving scheduled product they were not entitled to receive due to their DEA registrations are not being reviewed and set-up correctly in the computer system.

DEA schedule II paperwork is not kept separated from other documents.

There is no system to determine excessive or suspicious ordering by customers of controlled substance products.

Upon review of Purchase and Sales DEA Forms 222, several errors were found, including improper corrections, alterations by customers and data missing.

Controlled substance returns to vendors are shipped without proof of delivery.

Destruction and Thefts/Losses of ARCOS reportable items are not being consistently reported to ARCOS

Periodic inventories are not marked open or close of business, signed by the person conducting the inventory or witnessed. ARCOS and Biennial inventories are not marked open or close of business or dated.

- **OSHA**

Few issues noted in the OSHA portion of this audit constitute a significant when considered individually; however, because of the significant number of OSHA issues (15), OSHA compliance is considered a significant issue.
Items in this section include lack of safety committee, no OSHA monthly training, missing OSHA Plans for Lockout/Tagout, Hazard Communication, Fire Prevention and Plant Emergency Organization, no Personal Protective Equipment assessments and no documented fire equipment or shower/eyewash inspections.

- **DOT**

The facility was unaware they are handling hazardous materials. Required training and shipping documents are not in place.

- **FDA**

Prescription Drug Marketing Act (PDMA) training has not been conducted.

Customer returns are accepted without requiring the customer to document the product has been handled and stored properly.

These issues must be addressed immediately and corrective action completed within thirty days of receipt of this assessment report.

STATE OF COMPLIANCE:

This was the initial assessment at the Birmingham facility.

DEA

In addition to Significant Issues listed above, the following observations are noted:

DEA Quarterly Exception Report is not used to verify customers' licensure is still active.

The facility alarm system is not being tested by facility personnel or the security company.

OSHA

See Significant Issues above

DOT

See Significant Issues above

FDA

In addition to Significant Issues listed above, the following observations are noted:

Temperature and humidity is not being monitored in the cage and vault coolers. Only three recorders are utilized to monitor the 290,000 sq ft warehouse.

The facility relies on the Germantown site for recall information. The difficulty in retrieving required recall documentation presents a risk should FDA perform a Recall Effectiveness Check at the Birmingham site. In addition customer responses to recalls are not monitored and second notifications sent to customers not responding to Class I and II recall notices.

Pharmaceutical Distribution
Birmingham, AL
June 26 – June 29, 2006

Drug Enforcement Administration Requirements

1. **Observation:** The DEA Quarterly Exception Report (N.T.I.S. Tape) is not part of account DEA verification.

B3 **Corrective Action:** Use Quarterly DEA Exception Report in the verification process of DEA licenses. Maintain the reports in accordance with state and federal record retention. (Cardinal Policy)

2. **Observation:** The facility is not submitting DEA Form 106s to DEA no later than 7 days after discovery of the theft or loss of a controlled substance.
   - 1 form out of 29 was not completed with the date of the loss
   - 3 of the 29 were reported beyond the 7 day reporting requirements

A3 **Corrective Action:** DEA requires notification to the local field office of any theft or significant loss upon discovery of such theft or loss. Immediately notify the local DEA office in writing via fax if it is determined that a loss in transit or significant inventory discrepancy resulting from a theft or loss of a controlled substance product is discovered. File a DEA Form 106, Report of Theft or Loss of Controlled Substances, within 7 days of the incident. (21 CFR 1301.74 (c))

3. **Observation:** Two customers were found to have DEA schedules for which they are not licensed entered in the IT system controlling sales to customers, thereby allowing the customer to order those products.
   - 1 customer was not entitled to DEA schedule IIN
   - 1 customer was not entitled to DEA schedule IIIN

A3 **Corrective Action:** Compare customer license copy to computer system customer set up to ensure that customers are set up to only purchase scheduled drugs for which they are DEA licensed. Review registration verification procedures with personnel. Have employees report any discrepancies to management immediately when discovered. (21 CFR 1301.74 (a))

4. **Observation:** There is no system in place to determine excessive purchasing of products covered under the Methamphetamine Control Act.

B2 **Corrective Action:** Create a system to determine excessive purchasing by customers of products covered under the Methamphetamine Control Act and report any excessive purchases to the DEA on a monthly basis. (21 CFR 1310.05)

Controlled Substance Security

5. **Observation:** The alarm system is not being tested regularly by the facility or the alarm company.

B3 **Corrective Action:** Walk test the alarm system on a monthly basis. Contact the alarm company and make arrangements for a yearly on-site inspection of the alarm system. (Cardinal Policy)

Controlled Substance Purchases

6. **Observation:** Three months of Class II purchase DEA Forms 222 were reviewed (approximately 300); 1 DEA Form 222 did not have the date received field completed.

A3 **Corrective Action:** As merchandise is received, complete the blue copy of the DEA Form 222 to show the number of packages received and the date received. Include the blue receiving copies in the month-end audit of completed order forms. (21 CFR 1305.13)

7. **Observation:** Many of the DEA Forms 222 used to buy back Schedule II products customers wish to return had the facility buy back paperwork attached to the forms.

A3 **Corrective Action:** DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. (21 CFR 1305.17(c))

Controlled Substance Order Filling

8. **Observation:** There is no system in place to determine excessive purchasing of controlled substance products.

A2 **Corrective Action:** Create a system to determine excessive purchasing by customers of controlled substance products and report any excessive purchases to the DEA on a monthly basis. Post charts of products and dosage limits in the cage and vault. Remind vault personnel they should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. When a narcotic order appears to be excessive, have a supervisor approve the DEA Form 222 before it is filled. (21 CFR 1301.74 & Cardinal Policy)

DEA Form 222

9. **Observation:** The activity of 887 customer executed DEA Forms 222 were reviewed for errors.
   - Two DEA Forms 222 had alterations by the customer.
   - Many DEA Forms 222 were not corrected properly when an error was made by the order filler.

A3 **Corrective Action:** Return a DEA Form 222 to the customer if the pre-printed information is altered in any way. If a single line item shows an alteration or change, cancel that line. Notify the customer in writing. If the order filler records incorrect information on the DEA Form 222, make the correction by drawing a line through and initialing and dating the incorrect entry and printing correct information above it. If space will not allow that process, then enter the correct information in the lower portion of the DEA Form 222, referring to the line number being corrected. (21 CFR 1305.12 & 1305.13 & 1305.19)

10. **Observation:** Executed DEA Forms 222 are not stored separately from other records. The forms had customer notification sheets attached to them.

A3 **Corrective Action:** DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. (21 CFR 1305.17(c))

Controlled Substance Vendor Returns

11. **Observation:** Controlled substance returns are not shipped with a Proof of Delivery.

A3 **Corrective Action:** Ensure that controlled substances returns to the vendor are accompanied by a return authorization from the vendor and a debit memo from the facility. Send with a request for proof of delivery. File proof of delivery forms at the facility with a copy of the debit memo. (Cardinal Policy)

Automation of Reports and Consolidated Orders System (ARCOS)

12. **Observation:** No destruction or thefts/losses of ARCOS reportable items have not been reported to ARCOS since 1/06. (Nine should have been reported.)

A2 **Corrective Action:** ARCOS reportable products reported on DEA Forms 106 must also be reported separately to ARCOS. Review forms

submitted to DEA and create appropriate transactions for ARCOS. Consult the ARCOS Registrant Handbook for guidance on appropriate ARCOS codes to use. (21 CFR 1304.33(e))

Periodic Controlled Substance Inventories

13. **Observation:** Periodic inventories are not marked open or close of business, signed by the person conducting the inventory or witnessed. The ARCOS and Biennial inventories were also not marked open or close of business or dated.

A2 **Corrective Action:** DEA requires that Biennial inventories be marked with the date of the inventory as well as whether it was taken at open or close of business. ARCOS inventories must be taken at close of business on December 31st and marked as such. Periodic inventories must be dated, marked open or close of business and signed and witnessed. These inventories are typically utilized by DEA during audits and must be appropriately marked to be useful. (21 CFR 1304.11 (a) & 1304.33 (b))

Physical Inventory Integrity Audit

14. **Observation:** The activity of 17 DEA schedule drugs was reviewed from 9/30/2005 - 6/27/2006. Even though all items balanced to zero, the process for the facility employees to determine accountability was very difficult and time consuming. The facility needs to start conducting accountability audits more regularly to familiar themselves with the process and computer system menus to achieve this.

A3 **Corrective Action:** Using internal reports from prior DEA audits on a regular basis would better prepare the facility for any regulatory or internal audits. In addition, a sample Selected Item Audit Report, currently in use at other Cardinal facilities for reconciliation purposes, may be obtained from Cardinal SCS Quality and Regulatory Compliance. This report style is very beneficial and easy to use for reconciliation activities. (Cardinal Policy)

Occupational Safety and Health Act (OSHA)

15. **Observation:** There is no current safety committee operating. There was a safety committee in place previously but it has not met in over 10 months.

B1 **Corrective Action:** Re-establish the safety committee including a representative from each shift and department. Have the committee meet monthly and keep meeting minutes on file, including old business, new business and accident review. (29 CFR 1910.119 App A & Cardinal Policy)

16. **Observation:** Monthly OSHA training is not conducted at the facility. Topics such as PPE, Fire Prevention, Lockout/Tagout, Hazard Communication, and Hazmat are not presented.

B2

Corrective Action: Conduct monthly safety training meetings with all employees. Document attendance at the meetings. Contact Cardinal SCS Quality and Regulatory Compliance for availability of pre-recorded training tapes in these areas. (Cardinal Policy)

17. **Observation:** The facility does not have required OSHA plans in place for Lockout/Tagout and Hazardous Communication.

B2

Corrective Action: Develop written plans for Lockout/Tagout and Hazardous Communication specific to the location. Sample plans can be provided by Cardinal SCS Quality and Regulatory Compliance. Once completed, review the written plans with all employees and obtain signatures to document receipt of this training. Keep written plans on file and make employees aware of their location for further review. (29 CFR 1910.1200 (a)(2))

18. **Observation:** The facility has not conducted Personal Protective Hazard Assessments or trained on Personal Protective Equipment which may be required.

B2

Corrective Action: Conduct Hazard Assessment Reviews of all functions at the facility to determine the personal protective equipment required to safely perform the task. As required Personal Protective Equipment (PPE) is identified, conduct and document training for employees. (29 CFR 1910.132 (a), (d) (1) & (f) (1))

Fire Prevention

19. **Observation:** The facility does not have a Plant Emergency Organization plan on file.

B2

Corrective Action: Develop a Plant Emergency Organization program, assigning responsibilities to specific personnel in the event of an emergency. Train these individuals in their assignments. Post the form in the facility and maintain a copy on file. Make changes to assignments as needed. (29 CFR 1910.38 (c) (2))

20. **Observation:** The facility does not have a written Fire Prevention Plan.

B2 **Corrective Action:** Develop a written plan for fire prevention specific to the location. Once completed, review the written plan with all employees and obtain signatures to document receipt of this training. Keep the written plan on file and make employees aware of its location for further review. (29 CFR 1910.39(b))

21. **Observation:** The facility does not have any documented fire inspections. When the fire department inspects the facility, they do not leave documentation of the inspection.

B1 **Corrective Action:** If the fire inspector does not provide documentation of the inspection, create a document to file specifying the date of the inspection and any observations noted by the inspector. (Cardinal Policy)

22. **Observation:** Fire inspections performed by the facility personnel are not documented.

A3 **Corrective Action:** Conduct and document weekly facility inspections of all fire prevention equipment. The Weekly Fire Prevention and Safety Inspection Form may be obtained from Cardinal SCS Quality and Regulatory Compliance. (29 CFR 1910.157 (c) (4))

Warehouse Safety

23. **Observation:** Idle pallet storage areas are over 6 feet in height.

C3 **Corrective Action:** Re-stack pallets. Remind employees that stacks of pallets are to be less than six feet high. (Cardinal Policy)

Operation of Warehouse Equipment

24. **Observation:** Although the battery charging area does contain the required Personal protective Equipment (PPE), the PPE is not being used while servicing powered industrial truck batteries.

B3 **Corrective Action:** As inspections and maintenance are conducted on powered industrial equipment, PPE must be used (29 CFR 1910.132 (d) (2))

25. **Observation:** Wheels are not being chocked while trucks are unloaded

A3 **Corrective Action:** Prior to trucks being unloaded, make sure wheel chocks or power hooks are being used. (29 CFR 1910.178 (m) (7))

Emergency Contacts, Required Emergency Kits and Stations

26. **Observation:** Emergency phone numbers are not posted in clear site for employees.

C3 **Corrective Action:** Complete and post the Emergency Phone Number signs throughout the facility. (Cardinal Policy)

27. **Observation:** The facility does not maintain a list of designated hazardous materials.

B3 **Corrective Action:** Determine which hazardous products are stocked at the facility and compile a list of those products. Include the list in the Hazardous Communications Plan. (29 CFR 1910.1200 (e) (1) (i))

28. **Observation:** There is no documentation to support monthly shower and eyewash stations being testing.

B3 **Corrective Action:** When testing emergency eye wash stations and showers on a monthly basis, document the testing. (ANSI Z358.1-2004 & Cardinal Policy)

29. **Observation:** A posting is not available to indicate the closest medical facility.

C3 **Corrective Action:** Post signs throughout the facility listing the closest emergency medical facility. (29 CFR 1910.151 (b))

Hazardous Materials Shipment/Ground

30. **Observation:** The facility has not performed Hazardous Materials handling training.

A2 **Corrective Action:** Each employee involved in handling hazardous materials must receive general awareness/familiarization training designed to provide familiarity with the Hazardous Materials Regulations requirements and enable the employee to recognize and identify hazardous materials consistent with the hazard communication standards in the regulations. (CFR 49 172.704(a)(1))

31. **Observation:** Hazardous material manifests are not being generated for fully regulated shipments of Isopropyl gallons of alcohol.

A1 **Corrective Action:** The Hazardous Materials Regulations (HMR) generally requires each shipment of hazardous materials to be accompanied by properly prepared shipping papers. The shipping paper may be a bill of lading, waybill, manifest, or other document provided it contains all the required information. Shipping papers need to be kept for a period of 375 days, either electronically or maintained via hard copy. (49 CFR 172.202)

32. **Observation:** Hazardous material shipments are not being marked, labeled and shipped according to CFR Title 49

A1 **Corrective Action:** Each hazardous material that will be offered for transport must be clearly described on the shipping paper using the applicable information from the Hazardous Materials Table. At minimum, this shipping description must include the following:

Proper Shipping name, Hazard Class or Division Number, Subsidiary Hazard Class(es) or Division number(s) entered in parentheses, N/NA Identification Number, UN/NA Identification Number, Packing Group, if required, the Total Quantity by net or gross mass, capacity, or as otherwise appropriate, and the number and type of packages. (CFR 49 172.202)

33. **Observation:** The facility does not have a copy of CFR Title 49.

C3 **Corrective Action:** Contact the U.S. Government Printing Office at 202-512-1803 and obtain a copy of the Code of Federal Regulations, Title 49. (Cardinal Policy)

Prescription Drug Marketing Act (PDMA)

34. **Observation:** PDMA Training is not being conducted or documented.

A3 **Corrective Action:** Training for employees who handle affected product should, in addition to teaching them to perform their jobs in a competent manner, provide them with an understanding of the PDMA requirements. Training should address the following areas as they relate to the employee's specific job function: ((21 CFR 203.32 (a)))

- Storage
- Examination of materials during receiving, order filling, and shipping
- Returns goods processing
- Damages and outdates
- Stock rotation
- Record keeping
- Security
- Applicable policies and procedures.

35. **Observation:** Customers are not required to document proper storage and handling of products prior to or at the time of return of the product.

A2 **Corrective Action:** Have customers sign an On-going Assurance Form, available from Cardinal SCS Quality and Regulatory Compliance, at time of new customer setup. Also add the on-going assurance statement to the credit forms and require a customer signature with each return. (Cardinal Policy)

36. **Observation:** Temperature and humidity levels are not being recorded in the cage cooler and vault cooler. In addition only three temperature recording devices are in use to monitor the ambient warehouse area. The warehouse is not monitored for humidity.

B3 **Corrective Action:** Record temperatures and humidity using a continuous recording device. Key the temperatures into a computer file to calculate the monthly average temperature and mean kinetic temperature. Place temperature/humidity recording devices in walk-in coolers. Calibrate the devices on an annual basis. Determine if it is reasonable that only three temperature recording devices for the entire ambient warehouse provide adequate documentation of the warehouse temperatures. Obtain devices which monitor humidity levels. (Cardinal Policy)

37. **Observation:** The facility does not have a spare temperature/humidity reader.

B3 **Corrective Action:** Obtain a spare recorder for use during down periods of calibration or maintenance of the regular recorders. (Cardinal Policy)

Product Recalls

38. **Observation:** The facility relies on the Germantown site for the recall notifications to customers. Retrieving required information from the Germantown site was very time consuming and concerning. Required recalls were not found and letters to customers were not on file.

B3 **Corrective Action:** The difficulty presented in retrieving required recall documentation presents a risk should FDA perform a Recall Effectiveness Checks at the facility. In light of the pending Germantown facility closure, create a process to handle recalls at the Birmingham facility. Cardinal SCS Quality and Regulatory Compliance may be of assistance in this area. (21 CFR 7.49 (a) & Cardinal Policy)

39. **Observation:** Customer returns for recalls are not being monitored and second notifications sent out if the customer did not respond to the first notification.

B3

Corrective Action: For Class I and Class II recalls involving a health hazard, monitor customer responses. The Cardinal Recall Information Sheet, available from Cardinal SCS Quality and Regulatory Compliance, may be used as part of the customer recall notification. This form provides a means for the customer to respond to the facility regarding their inventory levels of the recalled products. Three weeks from the date the customers were originally notified of the recall, customers who have not responded should be contacted by phone or a second mailing. Maintain all customer lists and responses in the recall file. (Cardinal Policy)

Exit Interview

An exit interview was conducted with Dan Tolar, Operations Manager of the Birmingham, AL facility. The deficiencies noted in this report were discussed and agreed upon. All personnel involved with the assessment were receptive and cooperative. We appreciate the facility's assistance and thank them for their cooperation.

AUDIT COMPUTATION CHART
CARDINAL HEALTH DIVISION: Birmingham, AL

AUDIT PERIOD:
BEGINNING DATE: 9/30/2005
THROUGH
ENDING DATE: 6/27/2006

DRUG NAME, STRENGTH, FORM	BEGINNING INVENTORY	RECEIVED	TOTAL ACCOUNTABLE	CLOSING INVENTORY	DISTRIBUTED	TOTAL ACCOUNTED	DEVIATION ( )#	( )%
AMPHETAMINE SALTOMBO 10MG CII	187	1617	1804	93	1711	1804	0	0.00%
OXYCONTIN 10MG TAB UD 25 CII	10	0	10	0	10	10	0	0.00%
KADIAN 20MG CAP SR 100 CII	58	207	265	0	265	265	0	0.00%
OXYCODONE/ASA4.88/3 25 TAB 100 CII	20	387	407	70	337	407	0	0.00%
DEMEROL 100MG/ML VIAL 20,ML CII	86	40	126	26	100	126	0	0.00%
ADDERALL XR 25MG CAPS 100 CII	106	760	866	47	819	866	0	0.00%
ACETAMINOPHEN/COD #4 TAB 100 CIII	23	30	53	4	49	53	0	0.00%
HYDROCODONE/APAP7 .5MG TAB 10 CIII	53	424	477	53	424	477	0	0.00%
BUTISOL SODIUM 30MG TAB 100 CIII	7	80	87	14	73	87	0	0.00%
ACETAMINOPHEN/COD #3 TAB 100 CIII	9	23	32	8	24	32	0	0.00%
COTUSS-V SYRUP SF AF PINT CIII	10	0	10	0	10	10	0	0.00%
CLONAZEPAM .5MG TAB 100 CIV	62	624	686	56	630	686	0	0.00%
XANAX .25 TAB 500 CIV	4	7	11	3	8	11	0	0.00%
DIAZEPAM 5MG TAB 1000 CIV	74	594	668	32	636	668	0	0.00%

AUDIT COMPUTATION CHART
CARDINAL HEALTH DIVISION: Birmingham, AL

AUDIT PERIOD:
BEGINNING DATE: 9/30/2005
THROUGH
ENDING DATE: 6/27/2006

DRUG NAME, STRENGTH, FORM	BEGINNING INVENTORY	RECEIVED	TOTAL ACCOUNTABLE	CLOSING INVENTORY	DISTRIBUTED	TOTAL ACCOUNTED	DEVIATION ( )#	( )%
TRIAZOLAM .25MG TAB 500 CIV	54	160	214	25	189	214	0	0.00%
CHERATUSSIN AC SYRUP 480ML CV	109	1008	1117	39	1078	1117	0	0.00%
MYTUSSIN AC SYRUP 480ML CV	6	117	123	14	109	123	0	0.00%